

Appl. No. 09/877,374

Reply to Office action of September 30, 2008

REMARKS/ARGUMENTS

Claims 1 to 5, 9 to 29, 62 to 70, 72, 74 and 75 are pending in this application. New claim 76 has been added and claims the method of claim 1 wherein the heterologous antibody lacks fucose which, as is discussed below, is at least inherent in the specification. This amendment includes no new matter.

The Examiner rejects claims 1 to 5, 9 to 17, 19 to 29, 62, 63 and 74 under 35 USC 103(a) as being obvious over the previously cited art including Dutillio when taken with Sanders and in further view of Mohammed and in further view of Michael. Applicant has shown that it has been determined that monoclonal antibodies produced in avian oviduct cells and deposited into eggs are not fucosylated citing Table 2 at page 1162 of Zhu et al, Nature Biotechnology (2005) vol 23, p 1159-1169. Applicant has pointed out that this lack of fucosylation in the oviduct cells of chickens is in contrast to what is seen in other cells of the chicken as seen in Graph A of Fig. 4 at page 483 of Raju et al (2000) vol 10, p 477-486. Applicant has also pointed out that this absence of fucose alters the therapeutic utility of monoclonal antibodies by increasing their potency which is shown, for example, at the first column, last paragraph of page 102 of Etches, Trends in Biotechnology (2006) vol 24, p101-102.

The Examiner states that though Zhu and Etches may point to the increased potency in antibodies produced utilizing oviduct cells of chickens, it is reiterated that the claims do not require increased potency or any particular antibody yield.

It is not required that the claims recite an increase in potency. The advantage of the method (production of afucosylated antibodies) is inherent. In addition, it is known that afucosylated antibodies can have an increased activity.

MPEP section 716.02(f) states that "evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded", citing In re Chu, 66 F.3d 292, 298099, 36 USPQ2d 1089 1094-95 (Fed. Cir. 1995). Furthermore, it is stated in 716.02(f) that "We have found no cases supporting the position that a patent applicant's evidence or arguments traversing a § 103 rejection must be contained within the specification. There is no logical support for such a proposition as well, given that obviousness is determined by the totality of the record including, in some instances most

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significantly, the evidence and arguments proffered during the give-and-take of *ex parte* patent prosecution." 66 F.3d at 299, 36 USPQ2d at 1095.

In addition, claim 76 has been added which claims the method of claim 1 wherein the heterologous antibody lacks fucose. The feature of lacking fucose is inherent in the specification since for one thing, as is made clear in the post filing evidence of Etches and Zhu, antibodies produced in avian oviduct cells will lack fucose.

The invention clearly yields unexpected results, i.e., a method which resulted in antibodies which are afucosylated would not have been expected prior to the date of filing. Accordingly, the rejections are improper and should be withdrawn.

Applicant has shown that the pending claims are unobvious and allowable and requests the Examiner to pass the above-identified application to allowance.

If any issues remain to be addressed in this matter, which might be resolved by discussion, the Examiner is respectfully requested to call applicants' undersigned counsel at the number indicated below.

Respectfully submitted,



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